



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0168]

Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff." The purpose of this guidance is to make recommendations on the appropriate language to include in the labeling of a medical product to convey that natural rubber latex was not used as a material in the manufacture of the product, product container, and/or packaging. FDA is concerned that statements submitted for inclusion in medical product labeling, such as "latex-free," "does not contain natural rubber latex," or "does not contain latex" are not accurate because it is not possible to reliably assure that there is a complete absence of the allergens associated with hypersensitivity reactions to natural rubber latex in the medical product.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael T. Bailey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G120, Silver Spring, MD 20993-0002, 301-796-6530, email: Michael.Bailey@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Contact with medical products containing natural rubber has been associated with anaphylaxis in individuals allergic to natural rubber latex proteins. Therefore, all medical devices and device packaging composed of or containing natural rubber latex, dry natural rubber,

and synthetic latex or synthetic rubber that contains natural rubber in the formulation are required to include a specific caution statement regarding the presence of these materials (e.g., "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions") in device labeling (21 CFR 801.437). The biological products regulations require that the package label or package insert declare the presence of known sensitizing substances, but do not specifically mention natural rubber latex (21 CFR 610.61(l)). Specific regulations for labeling of natural rubber latex content in medical products or their containers and/or packaging do not exist for drugs or veterinary products.

At this time, there are no regulations requiring the labeling of a medical product to state that natural rubber latex was not used as a material in the manufacture of a medical product, medical product container, or medical product packaging. However, some manufacturers have included the promotional statements "latex-free" or "does not contain latex" in medical product labeling to inform users that natural rubber latex, dry natural rubber, or synthetic derivatives of natural rubber latex were not used. FDA believes that these labeling statements are not sufficiently specific, not necessarily scientifically accurate, and may be misunderstood or applied too widely and, therefore, are inappropriate to be included in medical product labeling. Use of these terms may give users allergic to natural rubber latex a false sense of security when using a medical product. This guidance document provides recommendations for scientifically accurate labeling that can be used by manufacturers who wish to convey that natural rubber latex was not used as a material in the manufacture of a medical product, medical product container, or medical product packaging.

The draft of this guidance was made available in the Federal Register on March 11, 2013 (78 FR 15370). The comment period closed on June 10, 2013. A number of comments were

received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on labeling medical products to inform users that a product, product container, or product packaging was not made with natural rubber latex. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex; Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1768 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The collections of information in 21 CFR part 801 are approved under OMB control number 0910-0485 and the collections of information in 21 CFR part 610, subpart G, are approved under OMB control number 0910-0338.

The labeling provisions recommended in this guidance are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the recommended labeling is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 25, 2014.

Leslie Kux,

Associate Commissioner for Policy.